AUG 2 9 2002

510(k) Summary - ELECSYS® CK-MB STAT and ELECSYS® CK-MB Assays

K022654

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3831

Contact person: Sherri L. Coenen

Date prepared: August 8, 2002

Device Name

Proprietary name: ELECSYS® CK-MB STAT
ELECSYS® CK-MB
Common name: Electrochemiluminescent immunoassay for the detection of CK-MB

Classification name: Creatine Kinase Test

Device description

The ELECSYS® CK-MB STAT and Elecsys® CK-MB Assays are a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

The Elecsys® CK-MB application is identical to the Elecsys® CK-MB STAT assay, the only difference being the length of incubation (18 minutes vs. 9 minutes).

Intended use

Immunoassay for the in vitro quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma.

510(k) Summary - ELECSYS® CK-MB STAT and ELECSYS® CK-MB, continued

Predicate Device

We claim substantial equivalence to the currently marketed Elecsys® CK-MB STAT Assay. (K974421).

Reagent Summary

The following table describes the similarities and differences between the original Elecsys® CK-MB STAT and restandardized assays.

Characteristic	CK-MB STAT (original device)	CK-MB STAT (modified Device)	CK-MB (modified Device)
Intended Use	For quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma.	Same	Same
Indications for Use	Diagnosis of myocardial ischemia, e.g. in acute myocardial infarction, myocarditis, etc.	Same	Same
Sample types	Serum, plasma (Li-, Na-heparin, K_2-EDTA, Na-citrate)	Serum, plasma (Li-, Na- heparin, K_3-EDTA, Na-citrate)	Same
Assay	Two-step sandwich assay using biotinylated and ruthemium labeled antibodies and streptavidin microparticles with electrochemiluminescent detection	Same	Same
Antibodies	Murine monoclonal	Same	Same
Incubation time	9 minutes	9 minutes	18 minutes
Measuring range	0.100 - 500.0 ng/ml	Same	Same
Analytical specificity	0.100 ng/ml	Same	Same

510(k) Summary - ELECSYS® CK-MB STAT and ELECSYS® CK-MB, continued

Characteristic	CK-MB STAT (original device)	CK-MB STAT (modified Device)	CK-MB (modified Device)
Expected values	• Median in healthy individuals 1.2 ng/ml • Recommended threshold 5 ng/ml	• Median: women 0.97 ng/ml men 1.35 ng/ml • 97.5th percentile: women 2.88 ng/ml men 4.94 ng/ml • 99th percentile: women 2.88 ng/ml men 6.73 ng/ml	Same
Standardization	Calibrated against commercially available CK-MB test (microparticle immunoassay)	Calibrated against AACC CK-MB reference material (human recombinant CK-MB)	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 9 2002

Ms. Sherri L. Coenen
Regulatory Affairs Consultant
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k022654
Trade/Device Name: Elecsys® CK-MB STAT and Elecsys® CK-MB
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHY
Dated: August 8, 2002
Received: August 9, 2002

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A K022654

Device Name: ELECSYS® CK-MB

Indications For Use:
Immunoassay for the in vitro quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys® 1010 / 2010 and Modular Analytics E170 (Elecsys module) Immunoassay Analyzers.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022654

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A K022654

Device Name: ELECSYS® CK-MB STAT

Indications For Use:
Immunoassay for the in vitro quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

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